Serial No.: 10/577,679

Filed: April 28, 2006

Office Action Mailing Date: January 22, 2008

Examiner: NIEBAUER, Ronald T.

Group Art Unit: 1654

Attorney Docket: 31831

#### **REMARKS**

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 36-38, 44, 46, 53, 56, 58, 60, 62, 70 are in this Application. Claims 46 and 58 have been rejected under 35 U.S.C. § 102. Claims 44 and 70 have been rejected under 35 U.S.C. § 103. Claims 36-38, 44, 46, 53, 56, 58, 60 and 62 have been rejected under 35 U.S.C. § 112. Claims 56, 60 and 70 have been canceled herewith. Claims 36, 37, 44, 46, 53 and 58 have been amended herewith. New claims 71-74 have been added herewith.

In a telephone interview graciously granted by the Examiner on March 20<sup>th</sup>, 2008, the following issues were discussed.

With respect to the open and closed language of claims 36 and 37, Applicants' representative suggested a language which the Examiner tentatively indicated would overcome the rejection. In addition, it was agreed that non elected SEQ ID NOs:2, 4, 8 and 12 will be excluded from the claims so as to bring the application in condition for allowance.

# Amendments To The Claims

## 35 U.S.C. § 112 Rejections

The Examiner has rejected claims 36-38, 44, 46, 53, 56, 58, 60 and 62 under 35 U.S.C. 112, second paragraph, as being indefinite and failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner states that claim 37 uses the closed language of "consisting of" in reference to the peptide sequences, however dependent claim 60 recited that the peptide is a cyclic peptide which would require an additional element as compared to the peptide of claim 37, and as such the scope of claim 37 and dependent claims 53, 56 and 60 is unclear since the claims appear to be drawn to both open and closed language. The Examiner's rejections are respectfully traversed.

Serial No.: 10/577,679

Filed: April 28, 2006

Office Action Mailing Date: January 22, 2008

Examiner: NIEBAUER, Ronald T.

Group Art Unit: 1654

Attorney Docket: 31831

In order to expedite prosecution of this case, Applicants have elected to amend claim 53 to an independent form (a grammatical change which is not meant to change the scope of the claim) and cancel claims 56 and 60, to thereby overcome Examiner's rejections.

In addition, Applicants point out that newly added claim 73, pertaining to "a pharmaceutical composition comprising as an active ingredient the peptide of claim 37 and a pharmaceutically acceptable carrier or diluent", is in line with the closed language of claim 37. Support for new claim 73 can be found on Page 24 (lines 9-12) in the instant application as filed.

In addition, the Examiner states that claim 36 uses the open language "comprising" followed by the closed language "consisting" followed by a statement that broadens (up to 50 amino acids in length) from consisting of SEQ ID NO:6 and 10; and that dependent claim 38 states that the peptide is cyclic, and as such the scope of claim 36 and dependent claim 38 is unclear since the claims appear to be drawn to both open and closed language. The Examiner's rejections are respectfully traversed.

In order to expedite prosecution of this case, Applicants have elected to amend claim 36 to an open language which recites:

"An isolated peptide comprising the amino acid sequence set forth in SEQ ID NO:6 or 10, the peptide being no more than 50 amino acids in length." (Emphasis added);

to thereby overcome Examiner's rejections.

Accordingly, dependent claims 38 and new dependent 71 read on cyclic and linear form, respectively, of the peptide of claim 36. In addition, new dependent claim 72 reads on a composition for targeting a drug using the peptide of claim 36. Support for new claim 71 can be found on Page 18 (line 2) in the instant application as

Serial No.: 10/577,679

Filed: April 28, 2006

Office Action Mailing Date: January 22, 2008

Examiner: NIEBAUER, Ronald T.

Group Art Unit: 1654

Attorney Docket: 31831

filed. Support for new claim 72 can be found on Page 28 (lines 30-31) in the instant application as filed.

The Examiner further states that claim 46 uses the open language "comprising" followed by the closed language "consisting" followed by a statement that broadens (up to 50 amino acids in length) from consisting of SEQ ID NO:2, 6, 10 and 12; and that dependent claim 62 states that the peptide is cyclic, and as such the scope of claim 46 and dependent claims 58 and 62 is unclear since the claims appear to be drawn to both open and closed language. The Examiner's rejections are respectfully traversed.

In order to expedite prosecution of this case, Applicants have elected to amend claim 46 to depend from claim 36, to thereby overcome Examiner's rejections.

Applicants point out that such an amendment is in line with the "open language" used in claim 36, and with the limitations (linear or cyclic) described in dependent claims 58 and 62.

Applicants have further elected to amend without prejudice claim 44 to recite:

"A composition-of-matter comprising <u>a peptide which consists of the amino acid sequence set forth in SEQ ID NO: 6 and an additional peptide which consists of the amino acid sequence set forth in SEQ ID NO: 10" (Emphasis added);</u>

Support for amended claim 44 can be found in Page 4 (lines 4-7) in the instant application as filed.

In addition, Applicants have added new claim 74 which recites:

"A composition-of-matter comprising a peptide which comprises the amino acid sequence set forth in SEQ ID NO:6, wherein said peptide is no more than 50 amino acids in length, and an additional peptide which comprises the amino acid sequence set forth in SEQ ID NO:10, wherein said additional peptide is no more than 50 amino acids in length"

Serial No.: 10/577,679

Filed: April 28, 2006

Office Action Mailing Date: January 22, 2008

Examiner: NIEBAUER, Ronald T.

Group Art Unit: 1654

Attorney Docket: 31831

Support for new claim 74 can be found in Pages 3 (lines 28-31) and 4 (lines 4-6) in the instant application as filed.

In addition, in order to expedite prosecution of this case, Applicants have excluded the non-elected species of SEQ ID NOs:2, 4, 8 and 12 from all amended and new claims.

The Examiner further states that in the amendments made to claim 44 it is unclear if the reference to SEQ ID NO:4 is deleted as well, and as such it is unclear if claim 44 is drawn to SEQ ID NOs: 4, 6, 8, 10 and 12 or if the claim is drawn to SEQ ID NOs: 6, 8, 10 and 12.

Applicants point out that the current amendments made in claim 44 render moot Examiner's rejections.

Thus, in view of the above claim amendments and remarks Applicants believe to have overcome the 35 U.S.C. § 112, second paragraph rejections.

#### 35 U.S.C. § 102 Rejections

The Examiner has rejected claims 46 and 58 under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Cancer Letters 171, 2001, 153-164). Specifically, the Examiner states that Zhang teach the peptide p160 of sequence VPWMEPAYQRFL which is identical to SEQ ID NO:2 of the instant invention; that this peptide is less than 50 amino acids and is linear, chemically synthesized and at different peptide concentrations (present in diluent). The Examiner's rejections are respectfully traversed.

In order to expedite prosecution of this case, Applicants have amended claims 46 and 48 to exclude SEQ ID NO:2, thereby rendering moot Examiner's rejections.

Serial No.: 10/577,679

Filed: April 28, 2006

Office Action Mailing Date: January 22, 2008

Examiner: NIEBAUER, Ronald T.

Group Art Unit: 1654

Attorney Docket: 31831

In view of the above claim amendments and remarks Applicants believe to have overcome the 35 U.S.C. § 102 rejections.

#### 35 U.S.C. § 103 Rejections

The Examiner has rejected claims 44 and 70 under 35 U.S.C. 103(a) as being unpatentable over Puzas (US 2005/0112168) and Balian (WO 03/072593).

Specifically, the Examiner states that Puzas teach a peptide of sequence SAHGTSTGVPWP which is identical to SEQ ID NO:8 of the instant invention; that Puzas teach the peptide in compositions and for use in methods of regulating bone formation; that Puzas does not teach the peptide in combination with other peptides of the instant invention. In addition, the Examiner states that Balian teach a peptide of sequence LLADTTHHRPWT which is identical to SEQ ID NO:4 of the instant invention, compositions including the peptide and its use for enhancing bone repair; and since both Puzas and Balian teach methods for enhancing bone formation/repair using composition containing the particular peptides, one would be motivated to combine both peptides in a composition. The Examiner's rejections are respectfully traversed.

In order to expedite prosecution of this case, Applicants have amended claims 44 and 70 to exclude SEQ ID NO:8 and 4, to thereby render moot Examiner's rejections.

In view of the above claim amendments and remarks Applicants believe to have overcome the 35 U.S.C. § 103 rejections.

Serial No.: 10/577,679

Filed: April 28, 2006

Office Action Mailing Date: January 22, 2008

Examiner: NIEBAUER, Ronald T.

Group Art Unit: 1654

Attorney Docket: 31831

In view of the above amendments and remarks it is respectfully submitted that claims 36, 37, 38, 44, 46, 53, 58, 62, 71-74 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

Martin O. Mayuha

Martin D. Moynihan Registration No. 40,338

Date: May 7, 2008

### Enclosures:

- Petition for Extension (One month)
- Request for Continued Examination (RCE)